UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JOSEPH HARRINGTON, on behalf of himself and those similarly situated Plaintiff, v. TETRAPHASE PHARMACEUTICALS INC., GUY MACDONALD, JOHN CRAIG THOMPSON, and DAVID LUBNER, Defendants.	)	Civil No. 16-10133-LTS
DAN SCHLAPKOHL, on behalf of himself and those similarly situated Plaintiff, v. TETRAPHASE PHARMACEUTICALS INC., GUY MACDONALD, JOHN CRAIG THOMPSON, and DAVID LUBNER, Defendants.	)	Civil No. 16-10577-LTS

ORDER ON MOTION TO DISMISS (DOC. NO. 70)

May 9, 2017

SOROKIN, J.

These consolidated class action cases allege that between March 5, 2015, and September 8, 2015, (the class period) Tetraphase Pharmaceuticals, Inc., and three individual defendants, Guy MacDonald, President and CEO, John Thompson, COO during the class period, and David

Lubner, CFO and senior vice president during the class period, violated securities laws. Plaintiffs allege that the defendants (collectively "Tetraphase") knew that the drug they were testing would fail long before that information was released to the public. Tetraphase filed a Motion to Dismiss, Doc. No. 70, Plaintiffs opposed, Doc. No. 74, Tetraphase replied, Doc. No. 75, and the Court held a hearing, Doc. No. 77. For the reasons stated below, the Motion to Dismiss is ALLOWED.

FACTS

A. Background

The allegations set forth in the Complaint,[1] Doc. No. 62, surround Tetraphase's clinical testing of eravacycline, a broad-spectrum tetracycline-derivative antibiotic. Id. at 11. The Court summarizes the relevant and material factual allegations from the lengthy Complaint.

A lab at Harvard University discovered a fully synthetic process to develop tetracyclines. Id. Previously existing conventional development methods were semi-synthetic and allowed only limited chemical diversity. Id. Harvard granted Tetraphase the exclusive rights to develop eravacycline using the fully synthetic process under a license agreement on August 3, 2006. Id. at 18. The licensing agreement required Tetraphase to successfully complete each stage of human clinical trials and submit a new drug application (NDA) to the FDA within specified timeframes. Id. The agreement deemed any failure to meet these goals a material breach permitting Harvard to terminate the agreement and reassert its rights over eravacycline. Id.

Tetraphase received external funding for the development process from the Biomedical Advanced Research and Development Authority (BARDA), a small government agency, under a contract that required Tetraphase to meet certain development milestones between February 1,

[1] This is the Second Amended Class Action Complaint and the operative complaint in the case.

2012, and January 31, 2017. Id. at 100. Successful completion of those milestones made Tetraphase eligible for additional financing of up to approximately $39.8 million. Id. The contract required that Tetraphase complete all clinical development milestones by the "definitive performance deadline" of January 31, 2017. Id.

B. Eravacycline clinical testing

Eravacycline was developed through the IGNITE clinical development program which included two phase 3 clinical trials. Less relevant to this case, IGNITE 1 tested whether eravacycline was an effective treatment for complicated intra-abdominal infections (cIAIs). Id. at 2. At issue here is IGNITE 2 which tested the efficacy of eravacycline as compared to Levofloxacin, a currently-approved broad-spectrum antibiotic used in the treatment of complicated urinary tract infections (cUTIs). Id. Tetraphase hoped that eravacycline would prove to be an IV-to-oral transition therapy for the treatment of cUTIs. Id. at 1–2. The IGNITE 2 phase 3 trial consisted of two parts: a lead-in portion and a pivotal portion. Id. at 2. The lead-in portion "was designed to study the potential efficacy of Eravacycline and use clinical data to support selection of a drug-dosing regimen for the pivotal portion of the trial. The dosing regimen selected from the lead-in portion of IGNITE 2 as the most efficacious would be further tested in the pivotal IGNITE 2 to prove the efficacy of Eravacycline and, Defendants claimed, support the submission of a NDA to the FDA." Id. at 23.

1. Lead-in portion of IGNITE 2

The lead-in portion of IGNITE 2 began in December 2013 and patient enrollment was completed on June 19, 2014. Id. at 24. Tetraphase split approximately 120 patients into three groups. Id. One group received the active comparator, Levofloxacin, while the other two groups

received an eravacycline IV followed by either 200 mg oral eravacycline every 12 hours or 250 mg eravacycline every 12 hours. Id. at 25.

On September 2, 2014, Tetraphase announced the results of the lead-in portion of IGNITE2. Id. Tetraphase reported that eravacycline has positive first-line results. Id. "The results showed that the IV-to-oral 200 mg dose of Eravacycline had a 70.8% response rate, as compared to a 64.3% response rate in the 250 mg dose, and a 52.2% response rate for Levofloxacin." Id. The European trial results were 75.0%, 64.3%, and 56.5% respectively. Id. Thus, the results suggested that the lower oral dose of eravacycline was more effective than the higher 250 mg dose. Id.

2. Pivotal portion of IGNITE 2

On October 6, 2014, Tetraphase announced the initiation of the IGNITE 2 pivotal phase trial at the 200 mg dose. Id. at 26–27. The press release stated that:

> Initiation of the pivotal portion of the IGNITE 2 trial is an important milestone and we look forward to top-line data from the study in mid-2015. We believe eravacycline is a differentiated antibiotic candidate given its potential as an IV-to-oral transition therapy and its activity against a wide variety of bacterial pathogens, including multidrug-resistant Gram-negative bacteria. IGNITE 2 is the second study in our IGNITE pivotal program, which also includes IGNITE 1, a Phase 3 clinical trial of an IV formulation of eravacycline in complicated intra-abdominal infections. We expect to announce top-line data from IGNITE 1 early in the first quarter of 2015.

Id. at 27.

On March 11, 2015, Tetraphase announced a secondary offering of 4.3 million shares of common stock at $35 per share, a total offering size of $150 million. Id. at 29. In Tetraphase's Offering Prospectus, filed with the SEC on March 12, 2015, the company noted that it planned to use the proceeds from the offering "to fund pre-commercialization activities and prepare for commercial launch of eravacycline" and stated that its products were "a significant innovation in

the creation of tetracycline drugs that has the potential to reinvigorate the clinical and market potential of the class." Id. The prospectus also noted that "we expect to submit a NDA to the FDA by the end of 2015 and a marketing authorization application to the European Medicines Agencies in the first half of 2016." Id. Tetraphase raised approximately $173.1 million from the sale of 4.945 million shares of common stock at $35 per share before deducting the underwriter discount and commissions. Id.

On May 6, 2015, a Tetraphase press release noted that it had completed enrollment for the pivotal trial "recently." Id.

On September 8, 2015, Tetraphase announced that the pivotal portion of IGNITE 2 had failed to meet its primary endpoint compared to Levofloxacin. Doc. No. 62 at 30. In other words, the trial aimed to establish that eravacycline was as effective as (or at least not inferior to) Levofloxacin in an IV-to-oral therapy formulation; but the trial showed that eravacycline was less effective than Levofloxacin. After the announcement, Tetraphase's stock price dropped by 80%, a $1.3 billion loss. Id. at 31. Throughout the class period and up until the day of the press release announcing that the eravacycline had failed, the individual defendants made large trades of Tetraphase stock. Id. at 31–32, 90–97. The trades were all made under 10b5-1 trading plans. MacDonald established his plan in November 2014 while Thompson and Lubner each established their plans in March 2015.[2] Id. at 81. On December 15, 2015, Thompson resigned from his position as COO. Id. at 31–32. On January 1, 2016, Lubner announced his resignations from his positions as CFO and senior vice president. Id. at 89.

[2] While the Complaint alleges that all of the trading plans were established in March 2015, Doc. No. 62 at 81, Tetraphase asserts in its Motion that MacDonald entered into his trading plan in November 2014, Doc. No. 71 at 32, an assertion Plaintiffs accept in their opposition, Doc. No. 74 at 28.

ANALYSIS

A. Legal Standard

"Under the PSLRA, as with any motion to dismiss under Rule 12(b)(6), we accept well-pleaded factual allegations in the complaint as true and view all reasonable inferences in the plaintiffs' favor."[3] ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008). "In order to survive a motion to dismiss, a complaint must allege 'a plausible entitlement to relief.'" Id. (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 560 (2007)). "For a complaint to state a claim for securities fraud under section 10(b) and Rule 10b-5, it must plead six elements: (1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation."[4] Id. (citing Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341–42 (2005)).

Under the PSLRA, a plaintiff's complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1).

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[3] In support of its motion to dismiss, Tetraphase included numerous documents, including the SEC form 10-K and press releases at issue and the individual Defendants' trade documents. See Doc. No. 72. "On a motion to dismiss, the court may properly take into account certain types of documents outside the complaint without converting the motion into one for summary judgment: (1) documents of undisputed authenticity; (2) documents that are official public records; (3) documents that are central to plaintiff's claim; and (4) documents that are sufficiently referred to in the complaint." Weaver-Ferguson v. Bos. Pub. Sch., Civ. A. No. 15-13101-FDS, 2016 WL 1626833, at *2 (D. Mass. Apr. 22, 2016) (citing Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993)). Here, the authenticity of the documents is not disputed by Plaintiffs and the documents are sufficiently referred to and extensively quoted in the Complaint. Additionally, Plaintiff raised no objection to the documents' inclusion. The Court will consider the documents with the Motion to Dismiss.

[4] Tetraphase does not challenge the reliance, economic loss, or loss causation elements.

Additionally, the scienter element requires the plaintiff to show "with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." Id. § 78u-4(b)(2)(A). "In this circuit, a plaintiff may satisfy the scienter requirement with a showing of either conscious intent to defraud or 'a high degree of recklessness.'" ACA Fin. Guar. Corp., 512 F.3d at 58 (quoting Aldridge v. A.T. Cross Corp., 284 F.3d 72, 82 (1st Cir. 2002)). "Recklessness in this context is a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care." Local No. 8 IBEW Retirement Plan & Trust v. Vertex Pharm., Inc., 838 F.3d 76, 80 (1st Cir. 2016) (quoting In re Smith & Wesson Holding Corp. Sec. Litig., 669 F.3d 68, 77 (1st Cir. 2012)). "The omission must 'present a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.'" Id. (quoting In re Smith & Wesson Holding Corp. Sec. Litig., 669 F.3d at 77) (alteration omitted). "While under Rule 12(b)(6) all inferences must be drawn in plaintiffs' favor, inferences of scienter do not survive if they are merely reasonable, as is true when pleadings for other causes of action are tested by motion to dismiss under Rule 12(b)(6)." Id. at 59 (quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 195 (1st Cir. 1999)). Scienter "should be evaluated with reference to the complaint as a whole rather than to piecemeal allegations" and "competing inferences should be weighed against plaintiffs' preferred interpretation of the facts." Id. A "strong inference" of scienter "must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Id. (quoting Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 314 (2007)).

Plaintiffs allege that various statements from eleven documents are actionable fraudulent statements. These documents are four press releases, three transcripts from conference calls, Tetraphase's annual report and Form 10-K for 2014, and two of Tetraphase's Form 10-Qs. In its submission, Tetraphase included all of those documents except the two Form 10-Qs. For each of the statements, Plaintiffs allege either all or some subset of the following reasons why the statements were materially false and misleading:

> (i) Eravacycline's chemical properties made it an ineffective treatment for cUTIs; (ii) Eravacycline would never be successful as an oral therapy; (iii) the Company inappropriately rushed into the pivotal portion of the IGNITE 2 trial without properly analyzing the inconsistent and nonsensical dose response results of the lead-in portion of the trial; (iv) as a result of (i) – (iii) Eravacycline would never meet its primary endpoint of statistical non-inferiority compared to Levofloxacin and the Company would not be able to submit a NDA to the FDA within the time periods stated in their public filings, if ever; (v) Eravacycline would have a much more limited market than represented; (vi) the Company had materially overstated the efficacy of Eravacycline and its business prospects; (vii) as a result of the above, Tetraphase's business prospects were far worse than represented; and (viii) the Company maintained inadequate internal controls.

Doc. No. 62 at 35–36.

B. Scienter Allegations

Plaintiffs make a few general allegations of scienter that would apply to all claims. [5] Central to these scienter allegations is the assertion that "[t]he Individual Defendants knew that

[5] Plaintiffs also allege that Tetraphase knew eravacycline would never be a suitable or marketable drug because of Tetraphase's frequent communications with the FDA about the trials. Doc. No. 62 at 4, 21–22. Plaintiffs vaguely argue that these reporting requirements are evidence of scienter. Doc. No. 74 at 34. The Court does not find the mere fact of communications with the FDA to be any evidence of scienter and, therefore, are certainly not strong evidence of scienter. Tetraphase's approval track with the FDA provided for more than the ordinary amount of communication between Tetraphase and the FDA. See, e.g., Doc. No. 62 at 20–21 ("In connection with its fast-track designation, the Company received substantial benefits in the form of frequent meetings with the FDA to discuss the drug's development, including early feedback on clinical trials, [and] frequent written correspondence from the FDA regarding the ongoing clinical development of Eravacycline . . . ."). In the absence of allegations that the FDA expressed concern or more (and there are no such allegations) or allegations that the fast track designation afforded defendants faster access to the results of the pivotal study than otherwise suggested by the allegations of the complaint (and there are no such allegations), these increased communications do not give rise to any inference of scienter let alone a strong inference of scienter. Indeed, if anything, the communications, on this record, would give rise to the contrary inference.

the Phase 3 IGNITE 2 pivotal trial had failed *more than four months* before they publicly disclosed the results to investors . . . .” Doc. No. 62 at 80 (emphasis in original). Plaintiffs allege in their Complaint that Tetraphase knew about the pivotal trial results “at least by April 20, 2015.” Doc. No. 62 at 31. This assertion is based on the EU Clinical Trials Register which apparently indicated that the trial ended on that date. Id. at 29. In their Opposition, Plaintiffs amend this date to “by the beginning of May 2015 at the latest.” Doc. No. 74 at 34. They base this new date on a bit of mathematical gymnastics:

> Defendant MacDonald stated during a March 5, 2015 earnings call, the “global phase 3 clinical program [was] *nearing completion*” and the Company “look[s] forward to *reporting* top-line results from the pivotal portion of IGNITE 2 *mid-year*” thereby implying that the result would be reported in June 2015. According to Defendants, analyzing the trial results would “take longer than six weeks” (Defs.’ Br. At 16). Thus, they obviously anticipated having all of the data by the beginning of May 2015.

Id. at 34–35 (emphasis in original) (citations omitted). First, Plaintiffs math is just wrong. Whether the study concluded on April 20, 2015 (as alleged in the Complaint) or by the beginning of May 2015 (as asserted in the opposition to the Motion to Dismiss), Tetraphase could not possibly have the “results” by “April 20, 2015” as alleged in the Complaint. Plaintiffs state that it took Defendants six weeks to analyze and release the results of the lead-in trial after completing patient enrollment. In fact, according to the dates Plaintiffs alleged it took slightly over ten weeks. Patient enrollment was completed on June 19, 2014, and the results were released on September 2, 2014. Doc. No 62 at 24–25. Even if patient enrollment were completed at the start of May, a ten-week analysis period would indicate that the results would be ready for release in mid-July at the earliest. Plaintiffs are claiming that Tetraphase had the results the moment that enrollment was completed or shortly after. But Plaintiffs have not laid out any facts supporting the inference that they had the results before making the allegedly false statements. The only fact

Plaintiffs pointed to at the hearing to support such an inference was that Tetraphase would have wanted to know the results as soon as possible. That is insufficient to allow an inference the Plaintiffs had the results in the beginning of May.

Second, insofar as Plaintiffs are asserting that Tetraphase possessed the results long before the release date, they have failed to allege a factual foundation for that assertion. The initial substantially smaller phase took almost three months to analyze, on the present record concluding that evaluating Phase 2 would take only six weeks or less time than the earlier phase is not plausible. [6]

Third, Tetraphase's timing statements fail to bear the weight Plaintiffs put upon them. Anticipating results "mid-year" as Tetraphase said up until May 2015 does not mean that the results are anticipated at the exact midpoint of the year. The Court will not hold that a company stating that they anticipate results "mid-year" means that if results do not come out at the exact midpoint of the year the company has made a fraudulent statement. Moreover, even if "mid-year" meant the exact midpoint of the year, the technical midyear point is at the start of July, not June as Plaintiffs assert. Ten weeks prior to that is late April. Finally, in the May 6, 2015 press release, Tetraphase stated that it expected top-line date from IGNITE2 "to be available in the third quarter of 2015." Doc. No. 72-10 at 6. Subsequent statements also assert that the top-line results would be available in the third quarter. See Doc. No. 72-14 at 7 (June 23, 2015 conference call stating that results are "coming up in the next couple of months"). Unless Tetraphase had some idea of the adverse results prior to May 6, 2015, and nothing in the allegations makes such a conclusion plausible, the reasonable inference is that the duration of the

[6] The Court would also point out that Plaintiffs simultaneously state that the results should have been analyzed faster while asserting that the results of the smaller lead-in trial, which took about six weeks to analyze, were released "with apparently little time for analysis." Doc. No. 62 at 26.

analysis or delay, if it was delay, arose from factors other than fraud. And, ultimately, the results were released during the third quarter of 2015, in line with the company's May 6 statement. Additionally, Plaintiffs do not allege that there was any change in the market because of the delay, suggesting that investors did not see the delay as a significant change.

Plaintiffs also argue that for various reasons Tetraphase should have known that eravacycline would not be effective as an IV-to-oral therapy. The various scientific opinions both parties offer on the efficacy of eravacycline from a chemical perspective show that there was disagreement in the scientific community about the potential use of eravacycline as a treatment for cUTIs. Plaintiffs' argument that Tetraphase should have known that eravacycline's chemical properties made it ineffective as a treatment for cUTIs fails. First, the Court is doubtful that this allegation reaches the specialized form of recklessness used in securities fraud cases. See Local No. 8 IBEW Retirement Plan & Trust v. Vertex Pharm., Inc., 838 F.3d at 80 ("This form of recklessness is closer to a lesser form of intent than it is to ordinary negligence." (quotation marks omitted)). Second, courts have been clear that scientific opinions are just that: opinions. See In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 543 (S.D.N.Y. 2015) ("Courts have repeatedly held 'publicly stated interpretations of the results of various clinical studies' to be 'opinions' because 'reasonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions.'" (quoting In re Sanofi-Aventis Sec. Litig., 774 F. Supp. 2d 549, 567 & n.20 (S.D.N.Y. 2011))). An opinion is only actionable in this context if it is "without any reasonable basis" or "objectively false." In re Sanofi Sec. Litig., 87 F. Supp. 3d at 544. Plaintiffs have not alleged sufficient facts to pass that requirement. Additionally, courts have found statements about a drug's efficacy actionable where regulatory approval is stated as "a when not if proposition," Sanders v. AVEO Pharm., Inc., Civ. A. No. 13-11157-DJC, 2015

WL 1276824, at *6 (D. Mass. Mar. 20, 2015), or where the FDA has raised concerns with the company about the efficacy of the drug, In re Transkaryotic Therapies, Inc. Sec. Litig., 319 F. Supp. 2d 152, 160 (D. Mass. 2004). Tetraphase did not do the former and the Plaintiffs have not alleged the latter. Thus, Plaintiffs' various arguments about eravacycline's chemical properties fail as the allegations to not give rise to an inference of scienter. [7]

As to eravacycline's possibilities as an oral therapy, the First Circuit has noted that when a pharmaceutical company "ma[kes] the investment necessary to design and perform a study," the company "must have thought that positive results were possible, even if not probable." Local No. 8 IBEW Retirement Plan & Trust v. Vertex Pharm., Inc., 838 F.3d at 81. While the trial ultimately failed, Tetraphase's investment into eravacycline as an oral therapy is indicative of the company believing that the trial had at least a plausible chance of being successful. Plaintiffs assert that "despite knowing in December 2014 that it was unlikely that Eravacycline could effectively treat cUTIs due to low concentrations in the urine and low bioavailability," Tetraphase began the IGNITE2 trial. Doc. No. 62 at 23. But knowing that it was "unlikely" that

[7] The Court also notes that Plaintiffs' implication that Tetraphase concocted a scheme in order to keep the rights to eravacycline, Doc. No. 62 at 98–101, is not persuasive. Plaintiffs never explain the obvious logical failings of a company trying desperately to keep the rights to a drug that it simultaneously knew would prove to be ineffective. Given the closer monitoring as part of the fast track designation with the FDA and the BARDA funding here, scienter ab initio is not present on the allegations of the Complaint. Plaintiffs argument might fit if defendants had come to realize during development that eravacycline would not succeed as hoped, but they nonetheless pressed on to make material false representations for personal profit. Here, however, Plaintiffs lack sufficient allegations to support such a theory. The Court also notes a theory that Plaintiffs did not argue in their papers, but arises out of Plaintiffs' oral presentation: that at some point before Tetraphase received the final results of the pivotal trial in September 2015, the company received some preliminary results which indicated the failure of the trial. This theory fails because (a) no factual allegations support finding receipt of preliminary conclusions by any specific earlier point in time; and (b) Defendants made the last alleged misrepresentation on August 5, 2015, a date too far removed from September for the Court to conclude that Defendants had preliminary results prior to that statement.

the trial would succeed is not the same as knowing the trial would fail. The Complaint is devoid of any assertion that Tetraphase knew eravacycline would not be effective as an oral therapy or recklessly disregarded the possibility. It rests instead on assumptions with no basis in the alleged facts or on mere speculation. That is insufficient. Plaintiffs' arguments that Tetraphase knew eravacycline would never be an effective oral therapy fail to allow an inference of scienter.

Plaintiffs repeatedly state that the low bioavailability was sufficient to show Tetraphase that eravacycline would never be effective or was at least such a risk to the success of eravacycline that it had to be specifically disclosed. A few points, however, bear note. First, Plaintiffs have not alleged that the pivotal trial failed because of the bioavailability alone. In fact, eravacycline was effective against cUTIs in the pivotal trial; it just was not quite as effective as Levofloxacin (eravacycline was 14% less effective). Doc. No. 62 at 30. The allegations do not support the assertion that it was wholly ineffective. To blame the failure of the trial on bioavailability alone is not an inference these allegations permit. Plaintiffs have not shown that the low bioavailability at the outset was such an obvious and material risk that it had to be specifically disclosed. Eravacycline's biolavailability never changed before or during any phase of the studies. Yet, the lead-in trial showed promise and the pivotal study showed close to non-inferiority against Levofloxacin.[8] In other words, despite a substantially lower bioavailability rate than Levofloxacin, Eravacycline was almost as effective. Additionally, some of the

[8] Plaintiffs also argue that Tetraphase should have known there was a problem with eravacycline when the lead-in trial showed that the lower 200 mg dose was more effective than the 250 mg dose. The Court thinks that infers too much. The lead-in trial had small numbers and, as discussed above, where a company shoulders the cost of a clinical trial, the Court will presume that the company thought positive results were possible. The proper inference from Tetraphase making the choice to use the lower 200 mg dose is that Tetraphase believed that that the trial had a better chance of success than at the higher dose.

scientific literature at the time supported the potential use for eravacycline at these bioavailability levels. See, e.g., Doc. No. 75 at 4 n.6.

Plaintiffs also assert that scienter can be inferred from the trades the various individual defendants made. However, these trades were all made under Rule 10b5-1 trading plans. MacDonald established his 10b5-1 trading plan on November 25, 2014, and all trades were made under that plan.[9] See Doc. No. 72-16 at 3; Doc. No. 72-17 at 3; Doc. No. 72-18 at 3; Doc. No. 72-19 at 3; Doc. No. 72-20 at 3; Doc. No. 72-21 at 3; Doc. No. 72-23 at 3. Thompson established his 10b5-1 trading plan on March 13, 2015, and all trades were made under that plan.[10] See Doc. No. 72-24 at 3; Doc. No. 72-26 at 3; Doc. No. 72-27 at 3; Doc. No. 72-28 at 3; Doc. No. 72-29 at 3. Lubner established his 10b5-1 trading plan on March 13, 2015, and all trades were made under that plan. Doc. No. 72-30 at 3; Doc. No. 72-31 at 3; Doc. No. 72-32 at 3; Doc. No. 72-33 at 3. Notably, all three plans were executed before even Plaintiffs argue that defendants possessed results from the pivotal portion of the IGNITE 2 trial.

The purpose of Rule 10b5-1 trading plans "is to insure against being accused of having engaged in a stock sale 'on the basis of . . . adverse material non-public information.'" Stiegele ex rel Viisage Tech., Inc. v. Bailey, Civ. A. No. 05-10677-MLW, 2007 WL 4197496, at *13 (D. Mass. Aug. 23, 2007) (quoting Weitschner v. Monterey Past Co., 294 F. Supp. 2d 1102, 1117 (N.D. Cal. 2003)). The presence of a Rule 10b5-1 trading plan "rebuts an inference of scienter and supports the reasonable inference that stock sales were prescheduled and not suspicious." Id.; see In re Gildan Activewear, Inc., Sec. Litig., 636 F. Supp. 2d 261, 272 (S.D.N.Y. 2009)

[9] One Form 4 does not list the Rule 10b5-1 trading plan because it was merely the exercise of a stock option. See Doc. No. 72-22.

[10] One Form 4 does not list the Rule 10b5-1 trading plan because it was merely the exercise of a stock option. See Doc. No. 72-25.

("[Defendant's] sales, which comprise over 99% of the total insider trading, both by volume and value, were made pursuant to a non-discretionary Rule 10b-5-1 trading plan, which undermines any allegation that the timing or amount of the trades was unusual or suspicious."). But the use of a Rule 10b5-1 trading plan is not always enough to rebut an inference of scienter. The First Circuit has stated that "the defendants' use of 10b5-1 trading plans is not dispositive in light of the plaintiffs' allegation that those plans were executed after the beginning of the fraudulent scheme." In re Ariad Pharm., Inc. Sec. Litig., 842 F.3d 744, 754 n.6 (1st Cir. 2016); see Emps.' Ret. Sys. of Gov't of the V.I. v. Blanford, 794 F.3d 297, 309 (2d Cir. 2015) ("When executives enter into a trading plan during the Class Period and the Complaint sufficiently alleges that the purpose of the plan was to take advantage of an inflated stock price, the plan provides no defense to scienter allegations."). "Insider trading cannot establish scienter on its own, but it can be used to do so in combination with other evidence." Miss. Pub. Emps. Ret. Sys. v. Bos. Scientific Corp., 523 F.3d 75, 92 (1st Cir. 2008). "At a minimum, the trading must be in a context where defendants have incentives to withhold material, non-public information, and it must be unusual, well beyond the normal patterns of trading by those defendants." Greebel v. FTP Software, Inc., 194 F.3d 185, 198 (1st Cir. 1999). Because MacDonald's 10b5-1 plan predates the beginning of the class period, no scienter can be inferred from his trades. As to Thompson and Lubner, their trading plans were established on March 13, 2015.[11] Thus, to allow an inference of scienter

[11] At the hearing, Plaintiffs argued for the first time that the Court should draw the inference that the individual Defendants changed their Rule 10b5-1. They argue that, while two of the plans were entered into in March, no trades took place under the plans until May at which point the Defendants sold more than half of their holdings, allowing the inference that the Defendants changed the plans to allow the sales once they knew that the pivotal trial was unsuccessful. Nothing before the Court suggests that the Defendants altered their plans and, as discussed above, nothing before the Court supports the inference that the individual Defendants knew the results in May. The Court will not infer that the individual Defendants altered their trading plans.

Plaintiffs must be asserting that the fraudulent scheme began before March 13, 2015. As discussed above, that would not be a reasonable inference from the alleged facts. Thus, the trading pursuant to the plans fails to support an inference of scienter.[12]

Plaintiffs also point to the subsequent resignations of Lubner and Thompson as evidence of scienter. They assert that the resignations were "[c]uriously [t]imed," "sudden," and "suspicious." Doc. No. 62 at 89. The resignations were both nearly four months after the pivotal trial results were released. "The problem with the Plaintiffs' allegation is that they bring no other facts to support the conclusion that the resignations indicate scienter. The Plaintiffs rely solely on the timing of the resignations . . . . This is not enough to build up the scienter inference." Wachtenaw Cty. Emps. Ret. Sys. v. Avid Tech., Inc., 28 F. Supp. 3d 93, 112–13 (D. Mass. 2014). The timing of Lubner's and Thompson's resignations alone fails to raise an inference of scienter.

Considering all of the evidence together, these allegations fall far short of the strong inference of scienter necessary to support this claim. The Court will consider the allegations of scienter that are more specific to certain statements below.

C. PLSRA Safe Harbor for Forward-Looking Statements

Tetraphase claims that many of the challenged statements fall under the PSLRA safe harbor which protects a forward-looking statement if it is "identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement" or is "immaterial." 15 U.S.C. § 78u-5(c)(1)(A). For a cautionary statement to be "meaningful"

[12] Plaintiffs' attempts to cast doubt on the case law surrounding Rule 10b5-1 trading plans does not alter the binding First Circuit law on the topic. See Doc. No. 62 at 97–98.

within the meaning of 15 U.S.C. § 78u-5(c)(1)(A) it must be sufficiently specific. "Vague or boilerplate disclaimers are insufficient to invoke safe harbor protection." In re Sepracor, Inc. Sec. Litig., 308 F. Supp. 2d 20, 34 (D. Mass 2004) (quoting In re Amylin Pharm., Inc. Sec. Litig., No. 01-cv-1455-BTM, 2003 WL 21500525, at *7 (S.D. Cal. May 1, 2003)).

The First Circuit has stated that "we understand the statute to intend to protect issuers and underwriters from liability for projections and predictions of future economic performance, which are later shown to have been inaccurate." In re Stone & Webster, Inc., Sec. Litig., 414 F.3d 187, 212 (1st Cir. 2005). In evaluating forward-looking statements, "a court must examine which aspects of the statement are alleged to be false." Id. at 213. "The mere fact that a statement contains some reference to a projection of future events cannot sensibly bring the statement within the safe harbor if the allegation of falsehood relates to non-forward-looking aspects of the statement." Id. Thus, the PLSRA safe harbor "is intended to apply only to allegations of falsehood as to the forward-looking aspects of the statement." Id.

1. Cautionary Statements

Tetraphase's press releases included the following paragraph, entitled "Forward-Looking Statements:

> Any statements in this press release about our future expectations, plans and prospects, including statements regarding our strategy, future operations, prospects, plans and objectives, and other statements containing the words "anticipates," "believes," "expects," "plans," "will" and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: whether our cash resources will be sufficient to fund our continuing operations for the period anticipated; whether results obtained in preclinical studies and early or interim clinical trials will be indicative of results obtained in future clinical trials; whether eravacycline will advance through the clinical trial process on a timely basis; whether the results of the Company's trials will warrant regulatory submission and receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether, if eravacycline

> obtains approval, it will be successfully distributed and marketed; and other factors discussed in the "Risk Factors" section of our most recent Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 10, 2014. In addition, the forward-looking statements included in this press release represent our views as of March 5, 2015. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so.

Doc. No. 72-8 at 8–9 (March 5, 2015 press release). Each press release was accompanied by nearly identical statements with different dates. See Doc. No. 72-9 at 4 (April 27, 2015 press release); Doc. No. 72-10 at 8–9 (May 6, 2015 press release); Doc. No. 72-11 at 8 (August 5, 2015 press release).

Similarly, Tetraphase's Form 10-K included the following paragraph entitled "Forward-Looking Information":

> This annual report on Form 10-K contains forward-looking statements regarding, among other things, our future discovery and development efforts, our future operating results and financial position, our business strategy, and other objectives for our operations. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict." "project," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. You also can identify them by the fact that they do not relate strictly to historical or current facts. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. These risks and uncertainties include those inherent in pharmaceutical research and development, such as adverse results in our drug discovery and clinical development activities, decisions made by the U.S. Food and Drug Administration and other regulatory authorities with respect to the development and commercialization of our drug candidates, our ability to obtain, maintain and enforce intellectual property rights for our drug candidates, our ability to obtain any necessary financing to conduct our planned activities, and other risk factors. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this annual report on Form 10-K, particularly in the section entitled "Risk Factors" in Part I that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any

> future acquisitions, mergers, dispositions, joint ventures or investments that we may make. Unless required by law, we do not undertake any obligation to publicly update any forward-looking statements.

Doc. No. 72-3 at 5. The list of risk factors in the Form 10-K is extensive and detailed. See id. at 48–79.

All but one of the conference calls also began with a cautionary statement about forward-looking statements. For example, at the start of the May 6, 2015, conference call, a Tetraphase representative stated:

> Before we begin our formal comments let me remind you that during today's conference call we will be making forward-looking statements that represent the Company's intentions, expectations or beliefs concerning future events. These forward-looking statements are qualified by important factors set forth in today's press release and the Company's filings with the SEC which could cause actual results to differ materially from those in such forward-looking statements.
>
> Information discussed on today's call is accurate as of today and we do not intend to necessarily update the specific information in the future.

Doc. No. 72-6 at 3. The other statements were nearly identical. See Doc. No. 72-12 at 3 (March 5, 2015); Doc. No. 72-13 at 3 (August 5, 2015). Before the June 23, 2015 conference call, however, no such cautionary statement was made. However, at the end of the conference call transcript, the following disclaimer was included:

> In the conference calls upon which Event Transcripts are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies' most recent SEC filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

Doc. No. 72-14 at 10.

Additionally, while the two Form 10-Qs are not included in the documents Tetraphase provided to the court, the cautionary statements listing risk factors are quoted at length in the Complaint. See Doc. No. 62 at 51–56 (first quarter report); id. at 65–70 (second quarter report).

Plaintiffs assert that these warnings constitute "exactly the type of vague, boilerplate disclaimers that do not put investors on notice of known specific risks." Doc. No. 74. The Court disagrees. Tetraphase's warnings are anything but boilerplate; the statements identify specific risk factors including the clinical trial results and the possibility of the FDA not approving the drug. This is precisely what the law requires. See, e.g., In re Parametric Tech. Corp., 300 F. Supp. 2d 206, 218–19 (D. Mass. 2001) (finding a statement sufficient where "the last sentence refers to specific factors that might affect Parametric's revenues in the third quarter of 1998"). In fact, the statements made at the start of each conference call were nearly identical to those that were found sufficient in In re Parametric. See id. at 219. Similarly, the cautionary statement at the end of the June 23, 2015 conference call transcript was sufficient to invoke the safe harbor. Because the other warnings were all significantly more detailed than the cautionary statements from the conference calls, the Court finds that the various cautionary statements are sufficient to invoke the safe harbor as to any forward-looking statements contained in those documents.

While the cautionary statements remained largely unchanged over time, there were no major changes in the risks Tetraphase faced during this period. Thus, Slayton v. Am. Exp. Co., 604 F.3d 758, 773 (2d Cir. 2010), has no application here. In Slayton, the Second Circuit found that a consistent statement is insufficient when the underlying facts have changed. Thus, "[t]he consistency of the defendants' language over time despite the new information they received in early May 2001 belies any contention that the cautionary language was 'tailored to the specific future projection.'" Id. (quoting Inst. Investors Grp. v. Avaya, Inc., 564 F.3d 242, 256 (3d Cir.

2009)). That is not the case here. Tetraphase's cautionary statements identified risks that were present throughout the class period and did not omit any major risk factors. Additionally, unlike in Slayton, no new problem arose that warranted a change in the listed risk factors prior to the results of the pivotal trial.

The Court holds that cautionary statements in the press releases and conference calls were sufficient to invoke the PLSRA's safe harbor protection for any forward-looking statements contained therein. The Court now turns to analyzing whether the challenged statements were forward looking within the meaning of the PLSRA and, if not, whether the statements are actionable.

Forward-looking statements under the PSLRA are defined as (1) "a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items;" (2) "a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;" (3) "a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission;" (4) any statement of the assumptions underlying or relating to any [of the above];" (5) "any report issued by an outside reviewer retained by an issuer, to the extent that the report assesses a forward-looking statement made by the issuer;" or (6) "a statement containing a projection or estimate of such other items as may be specified by rule or regulation of the Commission." 15 U.S.C. § 78u-5(i)(1).

2. Tetraphase's Statements

Plaintiffs point to approximately 75 statements[13] from the 11 documents. In the interest of efficient resolution of the claims and because the statements are largely duplicative of each other the Court will consider them categorically. See In re Biogen Idec, Inc. Sec. Litig., Civ. A. No. 05-10400-WGY, 2007 WL 9602250, at *6–8 (D. Mass. Oct. 25, 2007) (employing a similar tactic), aff'd, N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35 (1st Cir. 2008). The following statements "describe emblematic examples of the alleged misleading statements." N.J. Carpenters Pension & Annuity Funds, 537 F.3d at 45 (footnote omitted).

i. NDA Submission

> We look forward to reporting top line results from the pivotal portion of IGNITE 2 mid-year and continue to target submission of a new drug application, or NDA, for both indications by year end.

Doc. No. 62 at 34 (March 5, 2015 earnings call). See id. at 33 (March 5, 2015 press release).

Plaintiffs take issue with various similar statements about the planned NDA submission. These statements fall squarely within the definition of forward-looking statements under the PSLRA. Plaintiffs' claim that Tetraphase knew at the time that eravacycline would never reach that stage. But the Complaint is entirely devoid of any factual allegations to meet their pleading obligations under the PSLRA or Rule 9(b). Plaintiffs rely on speculation about what Tetraphase should have known based on the chemical properties of eravacycline or based on what Plaintiffs describe as illogical results from the lead-in portion of the study. These vague allegations fall short of what the law requires.

ii. Market Potential

> We started 2015 in a strong position and we will continue executing on our strategy to maintain the momentum we have created.

[13] This is true if each bolded portion of the quoted language is considered a separate statement.

> We believe Tetraphase is well positioned to be a leader in the antibiotic space.
>
> I think there is definitely an opportunity to be in that blockbuster status with new antibiotics as we continue to see multi-drug resistance bacteria grow and no antibiotics being able to treat those effectively.

Doc. No. 62 at 35 (March 5, 2015 earnings call).

Statements discussing the potential market for eravacycline fall within the definition of forward-looking statements. The PLSRA includes in the definition of forward-looking statements "a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items" 15 U.S.C. § 78u-5(i)(1). Again, Plaintiffs rely on speculation that Tetraphase knew that eravacycline would fail as a cUTI drug. But there is nothing in the Complaint that leads to a reasonable inference that Tetraphase knew the drug would fail. And Plaintiffs acknowledge that, had eravacycline been successful as an IV-to-oral therapy, the market would have been massive. See Doc. No. 62 at 16–17. The use of "We believe" and "I think" further bolsters that the statement is an opinion about future potential and "a reasonable investor would understand that." Cody v. ConforMIS, Civ. A. No. 15-13295-GAO, 2016 WL 4132204, at *9 (D. Mass. Aug. 3, 2016). These statements fall within the safe harbor provision.

iii. Internal Controls

Plaintiffs allege that Tetraphase's internal controls were inadequate and thus various certifications that Tetraphase had complied with the requirements for internal controls were false statements. Plaintiffs fail to actually identify a false statement regarding the internal controls. Their argument is essentially that the internal controls were inadequate so the certifications were false. Plaintiffs fail to plead with any particularity how the internal controls were inadequate or which internal controls were inadequate. See Simon v. Abiomed, Inc., 37 F. Supp. 3d 499, 521

(D. Mass. 2014) (finding allegations that "rest[] on a hindsight deduction that because off-label marketing occurred, there must have been a failure of internal controls, for which defendants are responsible" insufficient to survive a motion to dismiss), aff'd sub nom. Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228 (1st Cir. 2015). These allegations are insufficient to withstand the Motion to Dismiss.

iv. Lead-In Trial Results

> Prior to that, we reported positive top-line results from the lead-in portion of IGNITE 2, our second pivotal Phase 3 clinical trial, which validated the activity and safety profile of IV-to-oral transition therapy in complicated urinary tract infections.

Doc. No. 62 at 33 (March 5, 2015 press release). See id. at 34 (March 5, 2015 earnings call).

Plaintiffs assert that this and similar statements are a misstatement of historical facts and thus not protected by the safe harbor. Plaintiffs claim that the assertion that the top-line results were "positive" and that the results "validated" the potential of eravacycline as an IV-to-oral transition therapy were "directly contradicted by known facts." Doc. No. 74 at 18. While it is true that the safe harbor does not apply, these statements are still not actionable. There is no allegation sufficient to give rise to a strong inference of scienter. Plaintiffs essentially assert that Tetraphase should have known that the statement contradicted facts that they should have gleaned from the data, namely that the low bioavailability meant eravacycline would never be effective as an oral therapy. To meet the scienter requirement, Plaintiffs would have had to allege, with supporting factual allegations, that the risk was so obvious that Tetraphase must have known that the eravacycline trial would fail, not merely that Tetraphase should have known. This they have not done.

v. First-Line Therapy

In the Complaint, Plaintiffs take issue with various references to eravacycline as a "first-line" therapy. Doc. No. 62 at 36–37 (2014 Annual Report). Plaintiffs fail to expound their theory in their briefing. So far as the Court can glean Plaintiffs' meaning from the Complaint, they allege that references to eravacycline as a first-line therapy are actionable because eravacycline would never be successful as a first-line therapy. Thus, the arguments are largely duplicative of those above: the chemical properties of eravacycline meant that it would never be effective as an oral therapy. For similar reasons, references to eravacycline's potential use as a first-line therapy are not actionable.

vi. Potential to Treat cUTIs as an IV-to-Oral Therapy

Plaintiffs point to a number of statements made by Tetraphase about the efficacy of eravacycline, including:

> Data from the IGNITE program has continued to build a differentiated profile for eravacycline. As a mono therapy, eravacycline demonstrates potent activity against a broad range of bacteria including the difficult to treat Multi Drug Resistant Gram-negative pathogens.
>
> Importantly, eravacycline is the only antibiotic in development to treat Multi Drug Resistant gram-negative's with an IV to oral transition therapy option.
>
> I think our drug is well differentiated versus the other compounds. That being said, we do need more than one product out on the market. I think eravacycline will have an important place for treating UTI and intra-abdominal infections, if approved.

Doc. No. 62 at 34–35 (March 5, 2015 earnings call).

These statements do not contain any false statements of fact. This is not a case where there are sufficient allegations that the statements when made were contrary to known facts. See In re Transkaryotic Therapies, Inc. Sec. Litig., 319 F. Supp. at 161–62 (finding that statements of present belief were "conceivably in direct contradiction to known facts" where the FDA had sent

a letter to the company questioning their clinical results). There are no allegations in the Complaint sufficient to give rise to the inference that Tetraphase knew that eravacycline had failed to meet its goals before making these and similar statements.

In sum, when all of the evidence is considered together, it still falls short of that required to show a strong inference of scienter. Thus, Plaintiffs' claims fail.

CONCLUSION

For the reasons stated above, the Motion to Dismiss, Doc. No. 70, is ALLOWED.

SO ORDERED.

/s/ Leo T. Sorokin
Leo T. Sorokin
United States District Judge